

COMMITTEE ON GOVERNMENT REFORM
TOM DAVIS, CHAIRMAN



MEDIA ADVISORY

For Immediate Release
September 25, 2006

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Davis To Lead Hearing on Medical Device Safety

- What:** Government Reform Committee Oversight Hearing,
"Medical Device Safety: How FDA Regulates the Reprocessing of
Supposedly Single-Use Devices"
- When:** Tuesday, September 26, 2006
10 a.m.
- Where:** ROOM 2154, RAYBURN HOUSE OFFICE BUILDING

The Committee on Government Reform will hold a hearing to examine the Food and Drug Administration's oversight and regulation of the use of reprocessed single-use medical devices.

To cut costs, many hospitals reuse medical devices designated for one-time use. For example, new biopsy forceps can cost \$60, but re-used forceps go for a little as \$15. Manufacturers say they can't guarantee the safety or effectiveness of single-use devices after they are reprocessed. Reprocessors say they have processed more than 40 million devices with no evidence of increased risk to patient safety.

At this hearing, the committee will assess FDA's regulation of the reprocessing industry and determine if more monitoring is needed to assure the safety of reprocessed devices.

WITNESSES

PANEL I

Dr. Daniel G. Schultz,
Director, Center for Devices and Radiological Health
Food and Drug Administration

Don Selvey
Senior Vice President, Regulatory Affairs and Quality Assurance
Ascent healthcare Solutions, Inc.

Dennis J. Toussaint
Director, Regulatory Affairs
SterilMed, Inc.

Stephen J. Ubl
President and CEO
Advanced Medical Technology Association